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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,281	04/30/2001	Beverly Lynn Mangold	38602.0003	1022

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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/844,281	Applicant(s) Mangold et al.
	Examiner Jennifer Graser	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-43* are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a monoclonal antibody which is specifically reactive against B.anthracis (and non-reactive against B.cereus or B.thuringiensis) and hybridomas which produce said antibody, classified in class 530, subclass 388.1.

II. Claims 16-20, drawn to a kit comprising an antibody which is specifically reactive against spores or vegetative cells of B.anthracis, B.thuringiensis or B.cereus and which incorporates a colloidal particle based lateral flow detection device, classified in class 435, subclass 975.

III. Claims 21-32, drawn to a method for producing a species-specific monoclonal antibody to one species of Bacillus, monoclonal antibodies made by the method and kits comprising said method, classified in class 424, subclass 130.1.

IV. Claim 35, drawn to an antibody which is specifically reactive against B.thuringiensis and non-reactive against B.cereus or B.anthracis, classified in class 530, subclass 387.1.

V. Claim 36, drawn to an antibody which is specifically reactive against B.cereus and non-reactive against B.anthracis or B.thuringiensis, classified in class 530, subclass 387.1.

VI. Claims 37, 38, 40 and 41, drawn to an isolated or recombinant antigen comprising an EA1 protein of the surface layer of B.anthracis, compositions comprising said protein and methods of vaccinating with said protein, classified in class 530, subclass 350.

VII. Claim 39, drawn to a method for detecting B.anthracis by using the EA1 protein, classified in class 435, subclass 7.4.

VIII. Claims 42 and 43, drawn to a therapeutic agent comprising antibodies to the EA1 protein and methods for treating, preventing or controlling B.anthracis infection through passive immunization methods, classified in class 424, subclass 164.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Group I may be used in methods other than passive immunization, i.e., they may be used in detection methods. Further, the antibody claimed in claim 1 does not specify that it binds to the EA1 protein and is therefore different.

Groups I and II comprise different antibodies because the antibodies of Group I are reactive against B.anthracis, but not B.cereus or B.thuringiensis. The antibodies of Group II can

be reactive against B.cereus and/or B.thuringiensis. Further, there is no lateral flow detection system in Group I and therefore the products are different.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the antibodies of Group I may be made by a different method than that described in Group III, i.e., the antibodies may be synthetically produced. Further, the antibodies of Group I are different from those of Group III because they have a specific specificity to B.anthracis while being non-reactive to B.cereus or B.thuringiensis. The method of Group III may make completely different Bacillus antibodies.

The antibodies of Groups I, IV and V are structurally different and possess different specificities and therefore are completely different products which are patentably distinct and independent. The protein of Group V is biologically, chemically and structurally different than the antibodies of Groups I, IV and V and is therefore a patentably distinct and independent invention.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case, the protein of Group VI may be used in methods other than detection, i.e., it may be used as an immunogen.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the literature search for the Groups is not coextensive, restriction for examination purposes as indicated is proper.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JGraser 3/30/03

JENNIFER E. GRASER
PRIMARY EXAMINER